EXHIBIT 97

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Office Of Air Quality Planning And Standards Research Triangle Park, NC 27711

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Air

RESIDUAL RISK
Report to Congress

EPA-453/R-99-001

RESIDUAL RISK
REPORT TO CONGRESS

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Air and Radiation
Office of Air Quality Planning and Standards
Research Triangle Park, North Carolina 27711

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Contents

List of Exhibits

Acronym List

ADI	Acceptable daily intake
AEGL	Acute exposure guidance level
AEL	Adverse effects level
AIHA	American Industrial Hygiene Association
AIRS	Aerometric Information Retrieval System
ARE	Acute reference exposure
ATSDR	Agency for Toxic Substances and Disease Registry
AWQC	Ambient Water Quality Criteria
BAF	Bioaccumulation factor
BCF	Bioconcentration factor
BMC	Benchmark concentration
BMD	Benchmark dose
CAA	Clean Air Act
CAS	Chemical Abstracts Service
CRARM	Commission on Risk Assessment and Risk Management
CWA	Clean Water Act of 1972
DDT	Dichlorodiphenyltrichloroethane
DNA	Deoxyribonucleic acid
DOE	Department of Energy
DWEL	Drinking water equivalent level
ED_{10}	Effective dose at 10 percent response
EFH	Exposure Factors Handbook
EHS	Extremely hazardous substance
EMAP	Environmental Monitoring and Assessment Program
EOM	Extractable organic matter
EPA	Environmental Protection Agency
ERPG	Emergency Response Planning Guidelines
FACA	Federal Advisory Committee Act
FEL	Frank effects level
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FQPA	Food Quality Protection Act
GACT	Generally Available Control Technology
GIS	Geographic information system
GLWQI	Great Lakes Water Quality Initiative
HAP	Hazardous air pollutant
HEM	Human Exposure Model
HEAST	Health Effects Assessment Summary Tables
HEC	Human Equivalent Concentration
HI	Hazard index
HQ	Hazard quotient
IDLH	Immediately dangerous to life and health

IEM	Indirect Exposure Model
IRIS	Integrated Risk Information System
ISCST3	Industrial Source Complex Short-Term 3
K_{oc}	Organic carbon-water partition coefficient
K_{OW}	Octanol-water partition coefficient
LEC_{10}	Lower 95% confidence limit on effective concentration at 10% response
LED_{10}	Lower 95% confidence limit on effective dose at 10% response
LOAEL	Lowest-observed-adverse-effect level
LOC	Level of concern
LOEL	Lowest-observed-effect level
MACT	Maximum achievable control technology
MCLG	Maximum contaminant level goal
MEI	Maximum exposed individual
MIR	Maximum individual risk
MOE	Margin of exposure
MRL	Minimum risk level
NAAQS	National Ambient Air Quality Standard
NAS	National Academy of Sciences
NCLAN	National Crop Loss Assessment Network
NESHAP	National Emission Standard for Hazardous Air Pollutants
NOAEL	No-observed-adverse-effect level
NOEL	No-observed-effect level
NRC	National Research Council
NRDC	Natural Resources Defense Council
NTI	National Toxics Inventory
OAQPS	EPA Office of Air Quality Planning and Standards
OERR	EPA Office of Emergency and Remedial Response
ORD	EPA Office of Research and Development
ORNL	Oak Ridge National Laboratories
OSW	EPA Office of Solid Waste
PAH	Polycyclic aromatic hydrocarbon
PAMS	Photochemical Assessment Monitoring Station
PCB	Polychlorinated biphenyl
PIC	Product of incomplete combustion
POM	Polycyclic organic matter
P2	Pollution prevention
QSAR	Quantitative SAR
RAC	Risk Assessment Council
RfC	Reference concentration
RfD	Reference dose
RSC	Relative source contribution
SAB	Science Advisory Board
SAR	Structure-activity relationship

SPEGL	Short-term public emergency guidance level
TCDD	2,3,7,8-tetrachlorodibenzo-p-dioxin
TEF	Toxic equivalency factor
TEQ	Toxicity equivalent
TRI	Toxics Release Inventory
TRIM	Total Risk Integrated Methodology
TRV	Toxicity reference value
TSCA	Toxic Substances Control Act
UATMP	Urban Air Toxics Monitoring Program
UF	Uncertainty factor
URE	Unit risk estimate
VOC	Volatile organic compound

Abbreviated Glossary of Technical Terms

acceptable daily intake (ADI): An estimate of the daily exposure that is likely to be without deleterious effect even if continued exposure occurs over a lifetime.

acute exposure: One dose (or exposure) or multiple doses (or exposures) occurring within a short time relative to the life of a person or other organism (e.g., approximately 24 hours or less for humans).

adverse environmental effect: Defined in CAA section 112(a)(7) as "any significant and widespread adverse effect, which may reasonably be anticipated, to wildlife, aquatic life, or other natural resources, including adverse impacts on populations of endangered or threatened species or significant degradation of environmental quality over broad areas."

assessment endpoint: An explicit expression of the actual environmental value that is to be protected, operationally defined by an ecological entity and its attributes. For example, salmon are valued ecological entities; reproduction and age class structure are some of their important attributes. Together "salmon reproduction and age class structure" form an assessment endpoint.

benchmark dose (BMD), benchmark concentration (BMC): An exposure level that corresponds to a predetermined level of response, such as 10 percent of test animals affected.

bioaccumulation: The net accumulation of a substance by an organism as a result of uptake from all routes of exposure (e.g., ingestion of food, intake of drinking water, direct contact, or inhalation).

bioaccumulation factor (BAF): The concentration of a substance in tissue of an organism divided by its concentration in an environmental medium in situations where the organism and its food are exposed (i.e., accounting for food chain exposure as well as direct chemical uptake).

bioconcentration: The net accumulation of a substance by an organism as a result of uptake directly from an environmental medium (e.g., net accumulation by an aquatic organism as a result of uptake directly from ambient water, through gill membranes or other external body surfaces).

bioconcentration factor (BCF): The concentration of a substance in tissue of an organism divided by the concentration in an environmental medium, typically in situations where exposure is by contact or uptake directly from that medium (e.g., the concentration of a substance in an aquatic organism divided by the concentration in the ambient water, in situations where the organism is exposed through the water only).

bootstrap analysis: A method of statistical analysis in which the user empirically constructs sampling distributions when data are limited.

chronic exposure: Multiple exposures occurring over an extended period of time or a significant fraction of the animal's or the individual's lifetime.

confounder: A condition or variable that may be a factor in producing the same response as the agent under study. The effects of such factors may be discerned through careful design and analysis.

default assumption: Defined by the National Research Council as "essentially policy judgments of how to accommodate uncertainties. They include various assumptions that are needed for assessing exposure and risk, such as scaling factors to be used for converting test responses in rodents to estimated responses in humans."

dose-response assessment: The quantitative characterization of the relationship between the amount of an agent (either administered, absorbed, or believed to be effective) and changes in certain aspects of the biological system (e.g., critical adverse effects) apparently in response to that agent.

drinking water equivalent level (DWEL): A lifetime exposure concentration protective of adverse, non-cancer health effects that assumes all of the exposure to a contaminant is from a drinking water source.

ecological receptor: A general term that may refer to a species, a group of species, an ecosystem function or characteristic, or a specific habitat. An ecological entity is one component of an assessment endpoint.

ED_{10} or EC_{10}: Dose or concentration associated with a 10 percent level of response.

extrapolation: An estimation of a numerical value of an empirical (measured) function at a point outside the range of data that were used to calibrate the function. The quantitative risk estimates for carcinogens are generally low dose extrapolations based on observations made at higher doses.

hazard index (HI): The sum of more than one hazard quotient for multiple substances and/or multiple exposure pathways.

hazard quotient (HQ): The ratio of a level of exposure for a single substance over a specified time period to a reference level (e.g., RfC) for that substance derived from a similar exposure period.

hazardous air pollutant (HAP): Defined by the CAA as any air pollutant listed under CAA section 112(b) (in this document, synonymous with air toxics).

human equivalent concentration (HEC): Exposure concentration for humans that has been adjusted for dosimetric differences between experimental animal species and humans to be equivalent to the exposure concentration associated with observed effects in the experimental animal species. If occupational human exposures are used for extrapolation, then human equivalent concentration represents the equivalent human exposure concentration adjusted to a continuous basis.

LED_{10}, LEC_{10}: The 95 percent lower confidence limit on the ED_{10} or EC_{10} (dose or concentration associated with a 10 percent level of response).

lowest-observed-adverse-effect level (LOAEL): The lowest exposure level at which there are statistically or biologically significant increases in frequency or severity of adverse effects between the exposed population and its appropriate control group.

margin of exposure (MOE): The ratio of the level or dose derived from a toxicity or epidemiologic study (e.g., the NOAEL, the dose associated with a 10 percent response rate, etc.) to the estimated exposure level or dose.

Monte Carlo method: A repeated random sampling from the distribution of values for each of the parameters in a generic equation to derive an estimate of the distribution of outputs of the equation.

no-observed-adverse-effect level (NOAEL): An exposure level at which there are no statistically or biologically significant increases in the frequency or severity of adverse effects between the exposed population and its appropriate control. In an experiment with several NOAELs, the regulatory focus is primarily on the highest one, leading to the common usage of the term NOAEL as the highest exposure without adverse effect.

octanol-water partition coefficient (K_{ow}): The ratio of a chemical's solubility in n-octanol to its solubility in water at equilibrium. The logarithm of this value is often used as an indication of a chemical's ability to bioconcentrate in organisms.

pharmacokinetics: The study of the absorption, distribution, metabolism, and excretion of chemicals in living organisms and the genetic, nutritional, behavioral, and environmental factors that modify these parameters.

primary effect: An effect where the stressor (e.g., chemical) acts on the ecological component of interest itself, not through effects on other components of the ecosystem (synonymous with direct effect).

reference concentration (RfC) or reference dose (RfD): An estimate (with uncertainty spanning perhaps an order of magnitude) of a continuous inhalation exposure or a daily exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious non-cancer effects during a lifetime.

relative risk: The ratio of incidence or risk among exposed individuals to incidence or risk among non-exposed individuals.

safety factor: see uncertainty factor.

secondary effect: An effect where the stressor acts on supporting components of the ecosystem, which in turn have an effect on the ecological component of interest (synonymous with indirect effects).

stressor: Any physical, chemical, or biological entity that can induce an adverse response (synonymous with agent).

uncertainty factor (UF): One of several, generally 10-fold factors, used in operationally deriving the RfD or RfC from experimental data. UFs are intended to account for: (1) the variation in sensitivity among the members of the human population; (2) the uncertainty in extrapolating animal data to the case of humans; (3) the uncertainty in extrapolating from data obtained in a study that is of less-than-lifetime exposure; and (4) the uncertainty in using LOAEL data rather than NOAEL data.

unit risk estimate (URE): The upper-bound excess lifetime cancer risk estimated to result from continuous exposure to an agent (e.g., chemical) at a concentration of 1 microgram per cubic meter in air or 1 microgram per liter in water.

Executive Summary

Purpose of Report

Section 112(f) of the Clean Air Act (CAA), as amended, directs EPA to prepare the Residual Risk Report to Congress on the methods to be used to assess the risk remaining (i.e., the **residual risk**) after control technology standards applicable to emission sources of hazardous air pollutants (HAPs)[1] have been promulgated and applied. CAA section 112(f)(1) contains several specific requirements for the Report, which are summarized in **Exhibit ES-1** along with a reference to where each is addressed in the Report. Though not specifically required to be included in the Report to Congress, EPA also presents a discussion of its residual risk assessment framework for addressing the requirements under section 112(f)(2) to promulgate standards, if required, to "provide an ample margin of safety to protect public health" or to set more stringent standards, if necessary, "to prevent, taking into consideration costs, energy, safety, and other relevant factors, an adverse environmental effect." EPA ecological risk assessment methods are also described in the Report.

EXHIBIT ES-1
CROSSWALK BETWEEN SECTION 112(f)(1) REQUIREMENTS AND REPORT

Section 112(f)(1) Provision	Discussed in Report
112(f)(1)(A) – Methods of calculating the risk to public health remaining, or likely to remain, from sources subject to regulation under section 112 after application of standards	Chapters 3 and 5
112(f)(1)(B) – The public health significance of such estimated remaining risk	Section 4.1.1
112(f)(1)(B) – The technologically and commercially available methods and costs of reducing such risks	Section 4.1.2
112(f)(1)(C) – The actual health effects with respect to persons living in the vicinity of sources	Section 4.2.1
112(f)(1)(C) – Any available epidemiological or other health studies	Section 4.2.1
112(f)(1)(C) – Risks presented by background concentrations of HAPs	Section 4.2.2
112(f)(1)(C) – Uncertainties in risk assessment methodology or other health assessment technique	Section 4.2.3
112(f)(1)(C) – Any negative health or environmental consequences to the community of efforts to reduce such risks	Section 4.2.4
112(f)(1)(D) – Recommendations as to legislation regarding such remaining risk	Section 4.3

[1] The CAA defines HAP as any air pollutant listed under section 112(b), and provides procedures for adding and deleting pollutants from the list. The terms "**hazardous air pollutants**," "**HAPs**," and "**air toxics**" are used throughout this Report synonymously to refer to the pollutants listed under section 112(b).

Background

The 1970 CAA mandated a health-based program that required EPA to identify and list HAPs based on human health criteria. EPA was to then promulgate standards (national emission standards for hazardous air pollutants, or NESHAPs) for each pollutant at a level that would ensure the protection of public health with "an ample margin of safety." In the 20 years following enactment of the 1970 legislation, EPA identified eight pollutants as HAPs and regulated sources of seven of them.

In the 1990 CAA Amendments, Congress shifted the focus from individual pollutants to industrial and commercial source categories, and a phased approach to controlling air toxics emissions was developed. In the first regulatory phase, EPA must promulgate national, technology-based emission standards for source categories emitting any of the 188 currently listed HAPs in amounts exceeding specific emission thresholds. The fundamental approach is the use of available control technologies or work practice changes to achieve emission reductions in a timely manner for as many of the listed HAPs as possible, without explicit consideration of a HAP's inherent toxicity and potential risk. This technology-based standards program is commonly referred to as the maximum achievable control technology (MACT) program. Regulation of air toxics emissions through the MACT program is expected to achieve significant reductions in emissions of HAPs. As of October 1998, 53 source categories have been subjected to MACT standards, resulting in estimated emission reductions of more than one million tons of HAPs per year as well as significant reductions in emissions of criteria pollutants through co-control.

In the second regulatory phase, the 1990 Amendments provide for a human health risk- and adverse environmental effects-based "needs test." In this phase, referred to as residual risk standard setting, EPA will consider the need for additional standards following regulation under section 112(d) to protect public health and the environment. Section 112(f) of the CAA specifies that such residual risk standards "provide an ample margin of safety to protect public health." Section 112(f) also requires EPA to determine whether residual risk standards are necessary to prevent "an adverse environmental effect," taking into consideration "costs, energy, safety, and other relevant factors" in deciding what level is protective.

Also included in the 1990 CAA Amendments are provisions that EPA study several specific topics. In accordance with this mandate, EPA has published a number of reports to Congress, including the Mercury, Great Waters, and Utilities Reports to Congress, and continues to study these and other special topics. Additionally, EPA currently is refining its strategy for reducing risks in urban areas resulting from the emission of HAPs. The draft *Urban Air Toxics Strategy* released in August 1998 proposes to address the problems of cumulative exposures to air toxics in urban areas through an integrated approach that considers stationary and mobile sources of urban air toxics. These programs, in combination with the residual risk program, will provide a coordinated federal approach to address air toxics.

In the absence of a strong federal air toxics program prior to passage of the CAA Amendments of 1990, many State and some local agencies began to respond to the air toxics problem by developing their own programs. Many States in the country currently have an air toxics control program in place addressing, at a minimum, new sources of toxic air pollutants. Some have their own regulations that allow them to actively control air toxics emissions to a level protective of human health; others rely on comprehensive policies or authority provided to implement the federal program. Some State and local programs are risk-based, while others are technology-based.

The State and local programs have made progress in protecting the health of their people and their environment from exposure to air toxics. A successful comprehensive air toxics program will be one that integrates the residual risk and other federal programs with State and local programs and strengthens those existing programs. Program integration will involve interactive sharing of expertise, data, analyses, and methodologies. Additionally, State and local authorities may complement the federal program by addressing local risk issues that may not be effectively addressed nationally.

EPA is fully committed to environmental protection that is founded on sound and credible science. Objective, independent peer review of the scientific and technical bases of the Agency's actions is critical to accomplishing the Agency's mission. Although most of the major references that form the foundation of this Report have undergone (or are currently undergoing) external peer review, EPA requested and obtained from its Science Advisory Board an independent evaluation of the presentation of risk assessment methods and supporting data. This final Report was developed in consideration of both the SAB review comments and the comments received during the public comment period.

Risk Assessment Methods and Their Development

Three external reports have greatly influenced the development of human health risk assessment methods for air toxics at EPA: (1) the National Research Council's (NRC) 1983 report on risk assessment; (2) the NRC's 1994 risk assessment report; and (3) the Presidential/Congressional Commission on Risk Assessment and Risk Management's (CRARM) 1997 report. The 1983 NRC report, entitled *Risk Assessment in the Federal Government: Managing the Process*, describes the four-step paradigm for risk assessment that continues to serve as EPA's model for human health risk assessments. In a follow-up report entitled *Science and Judgment in Risk Assessment* mandated by the 1990 CAA Amendments, the NRC observed that several themes were common to all elements of the risk assessment process and noted that these themes were usually the focal points for criticisms of specific risk assessments. The NRC's discussion of these points and their recommendations in the different areas were viewed as a way to increase the effectiveness and accuracy of the risk assessment process. This Report describes EPA methods and strategies, which have incorporated many of their suggestions. The third document, the 1997 CRARM report, builds on the methods presented in these NRC reports. Section 303 of the CAA Amendments of 1990 mandated formation of the CRARM in response

to unresolved questions about the approach EPA should take in determining whether significant risks to human health remain after the implementation of technology-based HAP emission controls under CAA section 112. The CRARM's framework fosters an integrated approach to addressing complex, real-world issues that affect more than one environmental medium and involve exposures to mixtures of chemicals.

Ecological risk assessment at EPA began in the 1970s primarily in two program areas, water quality and pesticide registration. In 1986, the Agency published standardized guidelines for deriving water quality criteria and separate standard evaluation procedures for estimating pesticides' effects. By the late 1980s, EPA recognized a need for consistency in evaluating ecological risks across program offices and a need to make its ecological research efforts more responsive to its risk assessment needs Agency-wide. In 1992, the Agency's Risk Assessment Forum published the *Framework for Ecological Risk Assessment*, which could accommodate all the diverse kinds of ecological risk assessments. Various Agency-wide efforts to improve ecological risk assessment have followed. In 1998, EPA issued *Guidelines for Ecological Risk Assessment*, which are the basis of the residual risk approach to ecological risk assessment.

The following text box summarizes the components of EPA's current risk assessment methodology. The 1998 ecological risk assessment guidelines present a general three-phase framework (problem formulation, analysis, and risk characterization) that is consistent with and also appropriate for human health risk assessment. The traditional human health risk assessment paradigm (described by NRC in 1983) includes components of the analysis and characterization phases of risk assessment. Because the problem formulation phase is appropriate for both ecological and human health risk assessment, the Agency will use the three-phase framework (inclusive of the NRC paradigm components) in both human health and ecological risk assessments performed for residual risk analysis of air toxics. Consistent with the CRARM and NRC reports and with risk assessment practices throughout the Agency, the risk assessment process for residual risk analyses includes the use of screening-level analyses, as appropriate, and additional analysis, when warranted, using more refined data and/or tools.

In addition to the improvements and refinements in risk assessment methods and guidance since the 1983 NRC report, there have been significant enhancements in the available data and tools for conducting risk assessments on air toxics. As knowledge has improved regarding the toxicology of environmental pollutants, EPA has responded by modifying assessment methods (e.g., the proposed revisions to EPA's carcinogen risk assessment guidelines). The development and revision of EPA human health risk assessment guidelines are shown in the text box below.

The number of hazardous air pollutants for which EPA has developed quantitative dose-response assessments for use in risk assessment has also substantially increased. However, as EPA's coverage does not yet include all 188 HAPs, residual risk assessment activities will

FRAMEWORKS FOR RISK ASSESSMENT

The NRC risk assessment paradigm, first described in 1983, consists of four steps.

- **Hazard Identification.** The first step in a risk assessment is to determine whether the pollutants of concern can be causally linked to the health effects in question (cancer and/or non-cancer). Factors such as the route of exposure, the type and quality of the effects, the biological plausibility of findings, the consistency of findings across studies, and the potential for bioaccumulation all contribute to the strength of the hazard identification statement.

- **Dose-response Assessment.** This step is the quantitative characterization of the relationship between the concentration, exposure, or dose of a pollutant and the resultant health effects. When adequate data exist, the typical end product of the dose-response assessment for non-cancer effects is the identification of a sub-threshold dose or exposure level that humans could experience daily for a lifetime without appreciable probability of ill effect. Sub-threshold short-term exposure levels are also under development. For cancer, the typical goal of this step is estimation of a full dose-response curve for low exposures.

- **Exposure Assessment.** EPA's current *Guidelines for Exposure Assessment*, published in 1992, provide the framework for this step. An exposure assessment for air toxics has four major components: (1) emissions characterization; (2) environmental fate and transport analysis; (3) characterization of the study population; and (4) exposure characterization for both inhalation and non-inhalation pathways.

- **Risk Characterization.** This step is where all the information from the previous steps is integrated to describe the outcome of the analysis, and where the uncertainty and variability in the results are described. EPA's 1995 *Guidance for Risk Characterization* is the foundation for this step of the process.

EPA's Ecological Risk Assessment Framework, presented in the 1998 Guidelines, describes three phases.

- **Problem Formulation.** In this phase, the problem is defined, the purpose of the risk assessment is articulated, and a plan for characterizing the risks is developed. Important steps include identifying assessment endpoints, developing the conceptual model, and preparing an analysis plan.

- **Analysis.** This phase involves evaluating how exposure to stressors might occur (characterization of exposure) and the relationship between stressor levels and ecological effects (characterization of effects).

- **Risk Characterization.** In this phase, the risk is estimated and described through integration of the exposure and ecological effects profiles generated in the analysis phase.

consider other sources of such information. Regardless of the endpoint of interest (acute or chronic non- cancer, cancer, or ecological effects), consensus toxicity values are preferred for conducting risk assessments. Regardless of the endpoint of interest (acute or chronic non-cancer, cancer, or ecological effects), consensus toxicity values are preferred for conducting risk assessments. For human health risk assessments, the preferred source of such information is the Agency's Integrated Risk Information System. Other Agency and outside sources will be consulted as needed. As assessments for some HAPs may be less current than others, the Agency will evaluate the appropriateness of these assessments in light of more recent credible and relevant information. For ecological risk assessments, a hierarchy of preferred data sources is more difficult to identify and may depend on the type of assessment (e.g., screening versus refined assessment, type of ecosystem at risk). EPA plans to establish data source hierarchies for each type of toxicity information to be used in residual risk assessments, and to continue to improve our ability to assess risks posed by all 188 HAPs.

The Agency's risk assessment tools (e.g., tools for dispersion modeling, exposure modeling, and uncertainty analyses) have also improved. The tools currently available have varying input data requirements and applications. In residual risk assessments, EPA will target the use of these tools such that resources are used most effectively and appropriately. Screening-level analyses will use simpler, less resource intensive tools, enabling the Agency to target use of more refined tools with greater resource needs where most appropriate. As the Agency gains experience and knowledge in air toxics risk assessment, it continues to improve and develop the tools for this area.

EPA HUMAN HEALTH RISK ASSESSMENT GUIDELINES

EPA has published final risk assessment guidelines that address the following areas:

- Mutagenicity (1986)
- Carcinogenicity (1986)
- Chemical mixtures (1986)
- Developmental toxicity (1991)
- Exposure assessment (1992)
- Risk characterization (1995)
- Reproductive toxicity (1996)
- Probabilistic analysis (1997)
- Neurotoxicity (1998)

Draft revisions have been issued for carcinogenicity (1996) and are under development for mixtures.

Other Items in CAA Section 112(f)(1)

Section 112(f)(1), parts (B) through (D), of the CAA lists several other items that this Report should contain in addition to a description of the residual risk assessment methods. These specific items, and EPA's approach to reporting on them, include the following.

Public health significance of risks remaining after application of a MACT standard (section 112(f)(1)(B)): Given the CAA schedule for MACT promulgation and for residual risk determinations, residual risk assessments for source categories have not yet been completed as of the date of this Report, and EPA is not able to report on the actual public health significance of any residual risks at this time. As the Agency completes residual risk assessments for individual source categories, public health significance will be evaluated, and public health information, as available, will be presented. The Agency considers the ample margin of safety concept as introduced in the 1970 CAA Amendments and as applied in the 1989 benzene NESHAP a reasonable approach to evaluate public health significance and to manage residual risks under CAA section 112.

The available methods for and costs of reducing residual risks (section 112(f)(1)(B)): Current controls on major sources, which include State actions and federal requirements in addition to requiring MACT on major sources, do not necessarily guarantee that HAP emissions will be reduced sufficiently to protect public health. EPA believes that methods to reduce emissions beyond MACT exist. However, it is not possible to determine specific methods or to estimate the costs to reduce residual risks because of the timing of this Report in relation to MACT standard implementation and residual risk analyses. The discussion provided in the Report focuses on several key factors that will influence available methods for and costs of reducing residual risk.

The current state of knowledge regarding actual health effects of HAPs on humans (section 112(f)(1)(C)): Very few well-conducted health effects studies have focused on air toxics exposures to populations near sources of HAPs, largely because of methodological and statistical limitations to such studies. For this reason, information on health effects of air toxics is primarily based on laboratory animal and occupational studies. Animal studies are available for many HAPs and provide information on the potential for adverse human effects, but usually evaluate chemicals at higher exposures than normally expected for human populations. In addition, physiology and metabolic pathways that affect responses may differ between animals and humans. Occupational human data provide evidence of human effects, but are often limited by a lack of clarity about actual exposure conditions and the fact that occupational exposures are typically higher than those resulting from the ambient air. Therefore, extrapolation from higher doses to lower environmental concentrations creates uncertainty. This Report presents a summary discussion of epidemiological data, laboratory data, and other study data. It also briefly describes how EPA intends to use these data and any actual source category-specific health effects data that may become available when residual risk assessments are conducted.

EPA's strategy for collecting and assessing epidemiological and actual health effects data (section 112(f)(1)(C)): EPA recognizes the difficulties that exist in obtaining actual health effects data and conducting valid epidemiological studies involving populations near HAP sources. However, EPA believes that it is useful to incorporate any available health effects/epidemiology data in the residual risk assessments and intends to use such data wherever possible in decision-making. In the data gathering stage, EPA will search the scientific literature for published epidemiological studies related to the specific source categories, HAPs, and/or locations studied. Where published epidemiological studies are unavailable, EPA will consider examining other human health data for evaluation of correlations between exposure and adverse human health effects. However, EPA expects that such data will rarely be available.

Assessing risks of background concentrations (section 112(f)(1)(C)): Background concentrations are defined generally as the levels of contaminants that would be present in the absence of source-related contaminant releases. Background concentrations come from either contaminants that may occur naturally in the environment or contaminants that are emitted by other (i.e., not the sources being assessed) anthropogenic sources. Narrowly defined for HAPs and the residual risk program, background concentrations are the levels of HAPs in environmental media that are attributable to natural and anthropogenic sources other than the source(s) under evaluation. At this date, EPA does not have comprehensive Agency-wide guidance or policies on incorporating background concentrations into risk assessments and risk management decisions. Furthermore, analyses of background concentrations and risks can be extremely data- and resource-intensive. EPA's general approach in previous risk assessments and risk management decisions has been to assess the incremental risk of a particular source or activity and compare that risk to an acceptable risk criterion. The residual risk program will continue to use this approach, although background concentrations may be considered in the more refined analyses for some source categories.

Uncertainty and variability in the estimation of residual risks (section 112(f)(1)(C)): The Agency recognizes and supports recommendations of NRC regarding evaluation of uncertainty and variability in risk assessment. As feasible and appropriate, EPA will follow these recommendations. The Agency has published several guidance documents addressing this issue, which will be used to guide our analysis. While the exact approach to be taken has not been finalized and may differ from source category to source category, a number of general approaches will be considered for addressing uncertainty and variability in residual risk assessments, including: (1) qualitative assessment; (2) multi-scenario approaches and limited sensitivity analysis; (3) systematic sensitivity analysis; and (4) Monte Carlo simulation and related probabilistic methods.

Negative health or environmental consequences to the community of efforts to reduce residual risks (section 112(f)(1)(C)): EPA recognizes the possibility of creating or transferring risks as an unintended by-product of actions that may be taken to reduce residual risks of HAPs. EPA intends, as part of the section 112(f) standard-setting process, to the extent feasible, to identify potential negative health and environmental consequences and consider the risk-risk tradeoffs associated with any standards established under the residual risk program. Where deemed necessary, EPA will conduct analyses of these tradeoffs at an appropriate level of detail.

Recommendations to Congress for legislative changes (section 112(f)(1)(D)): At this time, EPA believes that the legislative strategy embodied in the 1990 CAA Amendments provides EPA with adequate authority to address residual risks to public health and the environment and provides a comprehensive and flexible strategy for addressing a variety of air toxics risk concerns. Therefore, the Agency is not recommending any legislative changes.

Framework for Risk Assessment Under the Residual Risk Program

EPA has developed a residual risk assessment framework to implement the requirements of CAA sections 112(f)(2) through (6). Those sections require EPA to promulgate standards beyond MACT when necessary to provide "an ample margin of safety to protect public health" and to "prevent, considering costs, energy, safety, and other relevant factors, an adverse environmental effect." The objectives for residual risk activities under section 112(f)(2) are two-fold:

(1) Assess any risks remaining after MACT standard compliance; and

(2) Set standards for the identified source categories, if additional HAP emission reductions are necessary to provide an ample margin of safety to protect public health or, taking into account cost, energy, safety, and other relevant factors, to prevent an adverse environmental effect.

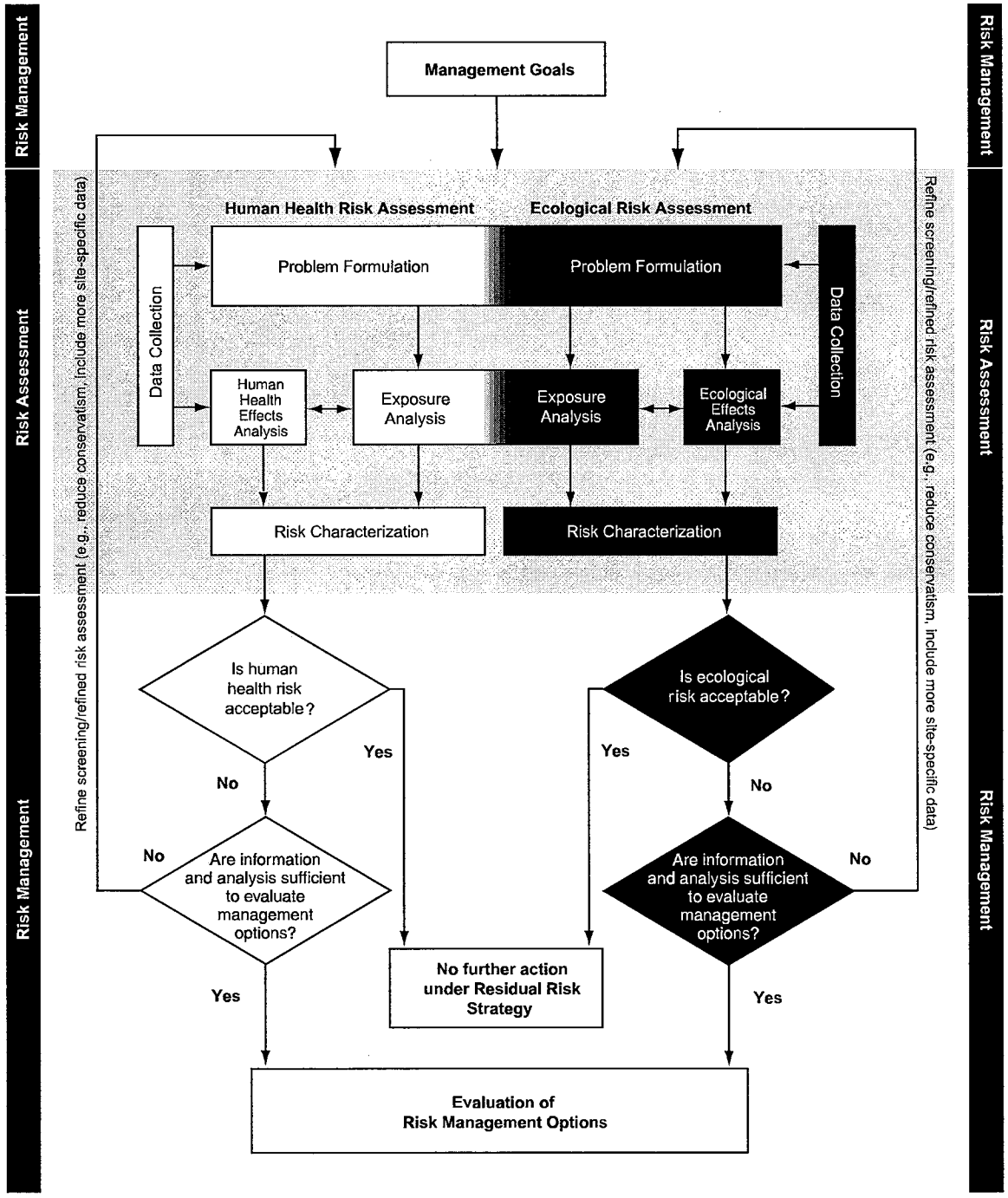
EPA's intent is to implement a residual risk assessment framework that will allow the Agency to be flexible in its decisions while ensuring that public health and the environment are protected. EPA's objectives also include integration of all portions of the federal air toxics program, continuing the partnership with State/local programs in the sharing of data and expertise, and including groups who may be affected by residual risk decisions (e.g., industry, public interest groups) as part of the process.

Using knowledge gained from past risk assessments, information from other regulatory agencies, and guidance from Reports such as the NRC and CRARM reports, the Agency has developed a general framework for assessing residual risks. **Exhibit ES-2** is a flowchart representation of the general residual risk strategy. This strategy calls for an iterative, tiered assessment of the risks to humans and ecological receptors through inhalation and, where appropriate, non-inhalation exposures to HAPs. The first component of the residual risk strategy is a statement of management goals. Those management goals help direct the problem formulation phase of both the human health and ecological risk assessments.

As shown in Exhibit ES-2, each human health and ecological risk assessment is organized into three phases: (1) the problem formulation phase, in which the context and scope of the assessments are specified; (2) the analysis phase, in which the HAPs' toxicity and exposure to humans or ecological receptors are evaluated; and (3) the risk characterization phase, in which the toxicity and exposure analyses are integrated to determine the level of risk that may exist. As illustrated in Exhibit ES-2, the problem formulation and analysis phases of the human health and ecological risk assessments will partially "overlap" in that some pathways of concern for humans (e.g., consumption of contaminated fish) may also be pathways of concern for ecological receptors (e.g., fish-eating wildlife). Consequently, exposure analyses for some HAPs may be designed to provide exposure assessments for both ecological and human health assessments.

In both human health and ecological risk assessments, there is essentially a continuum of possible levels of analysis from the most basic screening approach to the most refined, detailed assessment. The screening level or tier of analysis is designed, through the use of conservative inputs, to identify for no further action or analysis, situations or HAPs for which risks are unlikely to be of concern. Screening tier analyses are designed to be relatively simple, inexpensive, and quick, using existing data, defined decision criteria, and models with simplifying conservative assumptions as inputs. More refined levels of analysis include the refinement of aspects of the analysis that are thought to influence risk most or may contain the greatest uncertainty. At the refined tier, each analysis requires more effort, but produces results that are less uncertain and less conservative (i.e., less likely to overestimate risk). Under residual risk, an assessment will start at the level considered most appropriate upon examination of the available information during the scoping or problem formulation phase; iterations of the assessment, with refinements, will occur when warranted.

EXHIBIT ES-2
OVERVIEW OF RESIDUAL RISK FRAMEWORK
ITERATIVE APPROACH



Risk Management Decision Points

There will be many opportunities throughout the residual risk process for risk managers to make decisions that will determine the direction and scope of these assessments. Initially, EPA plans to set priorities for analyzing the more than 170 source categories based on a number of considerations, including the MACT promulgation dates for source categories (from which the statutory time period for residual risk determinations is measured) and any available information bearing on the relative level of residual risks attributable to various source categories. Following this, the problem formulation phase will determine how each risk assessment will be framed. For example, decisions regarding which HAPs, what exposure pathways, and what level of analysis (early screen or more refined) will be made. Much of the data that will feed these decisions will come from existing data that are easily accessible and determined to be adequate for this step.

The purpose of a screening analysis is to identify those situations or HAPS for which no further action is needed and those for which further analysis is needed. When a subsequent analysis is performed, those aspects of the analysis that are thought to influence risk most or contain the greatest uncertainty are refined. Although the screening analysis can serve as a basis for a decision to eliminate low-risk source categories from further consideration under section 112(f), it is not adequate to serve as a basis for establishing additional emission reduction requirements. The results of a more refined assessment can support either a conclusion of "no further action" or "additional emissions reductions may be needed," and will be used by EPA to make decisions on whether additional emission reductions are needed for individual source categories.

For public health risk management decision-making in the residual risk program, EPA considers the two-step process culminating with an "ample margin of safety" determination, as established in the 1989 benzene NESHAP and endorsed by Congress in the 1990 CAA Amendments as a reasonable approach. In the first step, a "safe" or "acceptable risk" level is established considering all health information including risk estimation uncertainty. As stated in the preamble to the rule for benzene, which is a linear carcinogen (i.e., a carcinogen for which cancer risk is believed or assumed to vary linearly with exposure), "an MIR (maximum individual risk) of approximately 1 in 10 thousand should ordinarily be the upper-end of the range of acceptability." In the second step, an emission standard is set that provides an "ample margin of safety" to protect public health, considering all health information including the number of persons at risk levels higher than approximately 1 in 1 million, as well as other relevant factors including costs, economic impacts, technological feasibility, and any other relevant factors. In notifying the public of the 1989 benzene NESHAP, the Agency stated that it "strives to provide maximum feasible protection against risks to health from hazardous air pollutants by (1) protecting the greatest number of persons possible to an individual lifetime risk level no higher than approximately 1 in 1 million and (2) limiting to no higher than approximately 1 in 10 thousand the estimated risk that a person living near a plant would have."

Thus, the benzene NESHAP established specific risk management policy for the protection of public health with an "ample margin of safety," and provided a specific application for public health risks posed by a linear carcinogen, including some numerical criteria, that will be used in addressing residual risks. Under this risk management policy, EPA is developing risk management framework applications to specifically address non-cancer public health risks and public health risks posed by carcinogens with non-linear risk assumptions. Further, the Agency is also developing a risk management framework to address adverse environmental effects in the residual risk program. None of these framework applications are presented in this Report.

Summary

This Report responds to section 112(f)(1) of the Clean Air Act and contains EPA's general framework for assessing risks to public health or the environment remaining after implementation of emissions standards under 112(d). EPA's risk assessment methods and the corresponding data and tools have developed substantially since the adoption of the 1990 Amendments containing this section. The Agency will apply these improved assessment methods, data, and tools, augmented as appropriate with current information or findings, in assessing the need for standards under section 112(f)(2). The residual risk assessment framework is intended to provide EPA with appropriate flexibility in its analyses and decisions while ensuring that public health and the environment are protected from air toxics as envisioned by Congress in the CAA.

1. Introduction

In 1990, Congress amended section 112 of the Clean Air Act (CAA) and mandated a new approach to the regulation of hazardous air pollutants (HAPs).[1] Under the original CAA (1970), air toxics were addressed through a risk-based program, and emission standards were set for individual pollutants. The new approach first requires the development of technology-based emission standards under section 112(d) for major and, in some cases, area sources of the currently listed 188 HAPs. The statute directs that these standards are to be developed over a 10-year time frame and based on the maximum achievable control technology (MACT). The Environmental Protection Agency (EPA) is currently in the process of developing MACT standards for more than 170 categories of HAP sources. As of October 1998, MACT standards had been promulgated for 53 source categories. When fully implemented, these standards are expected to result in estimated HAP reductions of approximately a million tons per year, plus more than two million tons per year of particulate matter and precursors to ground level ozone.

SECTION 112(f)(1) REPORT REQUIREMENTS

". . . the Administrator shall investigate and report, after consultation with the Surgeon General and after opportunity for public comment, to Congress on:

- Methods of calculating the risk to public health remaining, or likely to remain, from sources subject to regulation under this section after the application of standards under subsection (d) of this section;
- The public health significance of such estimated remaining risk and the technologically and commercially available methods and costs of reducing such risks;
- The actual health effects with respect to persons living in the vicinity of sources, any available epidemiological or other health studies, risks presented by background concentrations of hazardous air pollutants, any uncertainties in risk assessment methodology or other health assessment technique, and any negative health or environmental consequences to the community of efforts to reduce such risks; and
- Recommendations as to legislation regarding such remaining risk."

Section 112(f) of the CAA, in addition to requiring this Report to Congress (Report), calls for an evaluation of the health and environmental risks remaining after technology-based standards have been promulgated (i.e., the **residual risks**) and requires more stringent regulation if certain criteria are not met. Specifically, its focus is to achieve a level of protection that protects the public health with an "ample margin of safety" (see Section 2.1 for a discussion of this term) while also ensuring that "taking into consideration costs, energy, safety, and other

[1] The Clean Air Act defines hazardous air pollutant as any air pollutant listed under section 112(b), and also provides procedures for adding and deleting pollutants from the list. The terms "**hazardous air pollutants**," "**HAPs**," and "**air toxics**" are used throughout this Report synonymously to refer to the pollutants listed in the CAA under section 112(b).

relevant factors," residual emissions do not result in "an adverse environmental effect."[2] The accompanying text box outlines the requirements in section 112(f)(1) that this Report addresses.

1.1 Scope of Report

This Report responds to the statutory directives in section 112(f) of the CAA and also provides the general framework of EPA's strategy for assessing residual risk remaining from the HAPs being emitted from source categories subject to MACT standards. This chapter provides a brief introduction and describes the scope and organization of the Report. It presents the specific requirements for the Report listed in CAA section 112(f)(1) and briefly discusses each. Chapter 1 concludes with a discussion of peer review in the context of this Report. Chapter 2 provides a brief legislative and regulatory background on the CAA air toxics program in order to provide context for what follows. The Report then addresses, in Chapters 3 and 4, the required statutory elements of the Report, as shown in the text box on page 1. Chapter 3 provides information on the methods for conducting human and ecological risk assessments for emissions of air toxics, describes the data required, and discusses limitations in the available methods and data. As discussed in Section 3.1, the development of the Agency's risk-based program for air toxics has incorporated input from the National Research Council (NRC), the Commission on Risk Assessment and Risk Management (CRARM), State and local air toxics programs, and a variety of risk assessment policies and guidelines developed (and in some cases under development) by the Agency. Chapter 4 addresses the remaining statutory elements listed in CAA sections 112(f)(1)(B), (C), and (D) in the order listed in the CAA. In Chapter 5, the Report describes the Agency's strategy to conduct residual risk analyses as well as discusses other provisions in sections 112(f)(2) through (6) of the CAA. Appendix A provides the full text of CAA section 112(f), Appendix B provides relevant text from the preamble to the 1989 national emission standard for benzene, Appendix C presents the schedule for promulgation of MACT standards for industry source categories, and Appendix D provides a summary of EPA's responses to the major review comments of its Science Advisory Board (SAB).

The intent of this Report is to address the legislative requirements of section 112(f)(1) and to provide the reader with a basic understanding of the methods and process the Agency plans to follow in conducting risk analyses for air toxics. In response to section 112(f)(1)(A), the Report describes methods for human health and ecological risk assessment of air toxics. For these methods, the current availability and completeness of data or methodology are described along with how analyses will progress given the existing limitations (e.g., assessments will necessarily be limited to those HAPs for which toxicity information is adequate) and data and tool development activities. Methodology is presented in a descriptive manner rather than in

[2] The Clean Air Act at section 112(a)(7) defines adverse environmental effect as any significant and widespread adverse effect, which may reasonably be anticipated, to wildlife, aquatic life, or other natural resources, including adverse impacts on populations of endangered or threatened species or significant degradation of environmental quality over broad areas.

guidance form, with sufficient detail to inform the reader of the Agency's intentions and directions in performing "residual risk" and other air toxics analyses. Indicative of the Agency's desire to conduct analyses consistent with current, scientifically appropriate data and methodology, flexibility and the ability to incorporate changes in methodology and new data are essential to the process.

It is important to note that this Report does not contain the results of any residual risk analyses or a description of potential EPA actions after conducting such analyses (e.g., additional emission reductions for a given source category). The Agency is collecting existing data on source categories for which MACT standards have been promulgated and is beginning to analyze these data consistent with the framework described here.

In addition to risk assessment methods for residual risk, section 112(f)(1) specifies that EPA report on elements related to estimates of residual risk. The following section outlines the presentation of these additional elements within this Report.

Section 112(f)(1)(B)

Public Health Significance. Without having any actual residual risk analyses completed at this time, the Agency cannot draw conclusions about the public health significance of residual risks. However, the Agency considers the "ample margin of safety" concept, discussed in Section 2.1 of this Report, an appropriate basis for determining the significance of and for managing any residual risks for individual source categories. As residual risk assessments are completed for individual source categories, public health information, as available, will be identified along with risk estimates and attendant uncertainties and limitations as part of the risk characterization and decision-making process.

In making regulatory decisions for air toxics thus far, EPA has emphasized consideration of cancer risk to humans. However, air toxics can cause health effects other than cancer. EPA plans to consider non-cancer effects under the residual risk program. Although not available for discussion in this Report, the Agency currently is developing a policy framework for this management issue.

Technologically and Commercially Available Methods and Costs. This Report describes a range of control options for consideration if it is determined that additional control is needed. The Report provides an overview of these options, with an emphasis on pollution prevention (P2) approaches.

Section 112(f)(1)(C)

Acute Health Effects/Epidemiological and Other Health Information. The information available on actual health effects resulting from exposure to air toxics is limited. This Report presents a summary discussion of epidemiological data, laboratory data, and other exposure study data. It also briefly describes how the Agency intends to use these data and any actual source category-specific health effects data that may become available when residual risk assessments are conducted.

Risks Presented by Background Concentrations. This Report discusses general information on assessing risks posed by background levels of HAPs and presents a definition of background concentrations for air toxics and residual risk purposes. It describes approaches used by several EPA programs and includes examples of rules and guidance that consider the issue of background concentrations. It also presents a discussion of the difficulties in addressing background concentrations in residual risk analyses and identifies data needs to assess background. The discussion concludes by describing the Agency's options to analyze and consider background concentrations in residual risk analyses.

Uncertainties. This Report provides a general description of uncertainty in residual risk assessments and how uncertainty affects the level of confidence that can be placed in the estimates of risk. It also briefly presents approaches to addressing uncertainty and variability in the estimation of residual risks.

Negative Health or Environmental Consequences to Communities. In specifying that EPA report on negative health or environmental consequences to communities from efforts to reduce residual risks, section 112(f) indicates the importance of considering such potential consequences of risk management or risk reduction options. Pollution control technologies targeted at a single pollutant (e.g., a specific HAP) and single medium (e.g., air), especially conventional end-of-the-pipe treatment technologies, can inadvertently transfer pollutants and risks to different media, different locations, and different receptors, and can unintentionally create new and different risks in the process of controlling the targeted risk. Thus, as the Agency conducts residual risk analyses and before it takes subsequent standard-setting actions, efforts will be made, as feasible, to identify potential negative health and environmental consequences and to consider the risk-risk tradeoffs associated with any standards established under the residual risk program.

Section 112(f)(1)(D)

Legislative Recommendations. Section 112(f)(1)(D) requires EPA to investigate and report to Congress on "recommendations as to legislation regarding such remaining risk." Thus, if an unacceptable residual risk were identified, and no current authority within the CAA were determined to be adequate to reduce that risk, then the EPA would recommend an approach that

would assure that risk reductions would occur. However, the Agency believes that the regulatory approach embodied in the CAA is adequate for maintaining the goal of protecting the public health and environment, and, therefore, is not recommending any legislative changes.

1.2 Peer Review

The Agency is fully committed to environmental protection that is founded on sound and credible science. Objective, independent peer review of the scientific and technical bases of the Agency's actions is critical to accomplishing the Agency's mission. The Agency's commitment to credible, effective peer review is stated in its Peer Review Policy of June 7, 1994. Full implementation of this policy remains an Agency priority.

Although most of the major references that form the foundation of this Report have undergone (or are currently undergoing) external peer review, EPA requested that the SAB provide an independent evaluation of questions such as whether the Report identified the most relevant and useful methods of assessing risks from stationary sources and whether it properly characterized the types of data on which these methods rely. The Residual Risk Subcommittee of the SAB convened its review panel on August 3, 1998 to review the draft Report. Appendix D includes a summary of the Agency's responses to SAB's major comments. This final Report was developed in consideration of both the SAB review comments and the comments received during the public comment period.

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2. Background: Air Toxics Program

In order to understand the mandate of CAA section 112(f) and the purpose behind its charge to EPA, it is helpful to understand the legislative approach used to regulate HAPs in the 1970 CAA Amendments, the subsequent regulatory history in the 1970s and 1980s, and the legislative strategy behind the approach taken by the 1990 CAA Amendments. It is also useful as background to consider State and local air toxics programs and their role in EPA's air toxics program.

2.1 History of the Air Toxics Program: 1970-1990

Congress first required regulations limiting emissions of HAPs in 1970 by including an air toxics provision in the 1970 CAA Amendments. This provision described a health-based program that required EPA to identify and list HAPs based on human health criteria described in the Amendments. The EPA was to then promulgate standards for each pollutant, on a source category-by-source category basis, at a level that would ensure the protection of public health with "an ample margin of safety." After EPA listed a pollutant, regulation was required within a short time.

The EPA produced few air toxics regulations under the program established by the 1970 CAA Amendments. In the 20 years following the enactment of this legislation, EPA identified eight pollutants as HAPs and regulated seven of these. Impediments to regulation included the amount and type of data needed to establish a chemical as a HAP, emissions standards based on what the Agency interpreted to be solely human health effects considerations, extremely short statutory deadlines, and disagreements over how health effects should be assessed. A common theme running through many of these impediments to regulatory action was the lack of a consistent risk management framework with which to make regulatory decisions.

The most significant example of EPA's attempts to regulate HAPs under the 1970 CAA Amendments resulted in a DC Circuit Court decision that would guide the development of EPA's risk management approach for air toxics (Natural Resources Defense Council v. EPA 1987). Natural Resources Defense Council (NRDC) sued EPA on the Agency's attempt to establish a national emission standard for hazardous air pollutants (NESHAP) for vinyl chloride, stating that the Agency improperly used cost in regulating this HAP. The U.S. Court of Appeals for the DC Circuit Court agreed with NRDC, and in its decision presented a two-step framework by which to apply the "ample margin of safety" language: (1) first determine a "safe" or "acceptable risk" level, considering only public health factors, and (2) then set an emission standard that provides an "ample margin of safety" to protect the public health, considering relevant factors in addition to health, such as costs, economic impacts, technical feasibility, uncertainties, and other factors.

The 1989 NESHAP for benzene (EPA 1989a) presented the following risk management framework for cancer risk, which reflects the two-step approach suggested by the court. The benzene rule preamble states that in determining acceptable risk:

> The Administrator believes that an MIR [maximum individual risk] of approximately 1 in 10 thousand should ordinarily be the upper-end of the range of acceptability. As risks increase above this benchmark, they become presumptively less acceptable under section 112, and would be weighed with the other health risk measures and information in making an overall judgment on acceptability. Or, the Agency may find, in a particular case, that a risk that includes MIR less than the presumptively acceptable level is unacceptable in light of the other health risk factors (EPA 1989a).
>
> The EPA believes that the level of the MIR, the distribution of risks in the exposed population, incidence, the science policy assumptions and uncertainties associated with risk measures, and the weight of evidence that a pollutant is harmful to health are all important factors to be considered in the acceptability judgment (EPA 1989a).

The preamble also states that in the second step, where the standard is set with an ample margin of safety:

> EPA strives to provide protection to the greatest number of persons possible to an individual lifetime risk level no higher than approximately 1 in 1 million. In the ample margin decision, the Agency again considers all of the health risk and other health information considered in the first step. Beyond that information, additional factors relating to the appropriate level of control will also be considered, including costs and economic impacts of controls, technological feasibility, uncertainties, and any other relevant factors (EPA 1989a).

In the benzene NESHAP, EPA established risk management policy for the protection of public health with an ample margin of safety and provided a specific application for cancer risks such as those posed by benzene. Appendix B provides excerpts of the preamble text from the 1989 benzene NESHAP.

The HAP provisions of the 1970 CAA Amendments were written specifically in terms of public health effects, with no mention of ecological or environmental effects anywhere in section 112. In its original form, CAA section 112(b) directed that NESHAPs be set to provide ". . . an ample margin of safety to protect the public health . . ." In fact, HAPs were defined specifically in terms of human health; section 112(a) of the 1970 CAA defined a HAP as an air pollutant that ". . . may reasonably be anticipated to result in an increase in mortality or an increase in serious irreversible, or incapacitating reversible, illness." Thus, there was no legislative directive to consider environmental effects in regulating HAPs in the pre-1990 air toxics program.

2.2 Strategy For Air Toxics: Post-1990

Recognizing that the "health test" (i.e., the requirement for the protection of public health with an "ample margin of safety") was the most contentious part of section 112 under the 1970 CAA Amendments, Congress shifted the focus from individual pollutants to industrial source categories and developed a phased approach to controlling air toxics emissions in the 1990 CAA Amendments. Congress initially listed 189 HAPs in section 112(b), one of which has since been delisted by EPA (EPA 1996a). As part of the first phase of the new air toxics program, EPA must promulgate national, technology-based emission standards for sources in 174 source categories emitting any of the 188 listed HAPs above specific emission thresholds. The overall approach is to use available control technologies or work practice changes to get emission reductions in a timely manner for as many of the listed HAPs as possible, regardless of a HAP's inherent toxicity and potential risk. This technology-based standards program is commonly referred to as the MACT program.[3] Although there is no health test in this phase, it is intended that effective MACT standards will reduce a majority of the HAP emissions and much of the significant risk. It is expected that this program will reduce adverse environmental effects as well.

The revised air toxics legislative strategy embodied in the 1990 CAA Amendments maintains the goal of protecting the public health and preventing an adverse environmental effect and provides a more complete approach for dealing with a variety of adverse effects. The strategy recognizes that not all problems are national in scope or have a single solution. National emission standards must be promulgated to decrease the emissions of as many HAPs as possible from stationary major sources[4,5] and some area sources,[6] but authority is also provided to look at multiple source exposures in the urban environment and the deposition of HAPs to certain water bodies in order to address those specific concerns. In addition, there are mechanisms for increasing partnerships among EPA, States, and local programs in order to address problems specific to these regional and local environments.

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[3] MACT is defined as the emission standard specified in CAA section 112(d) as requiring the "maximum degree of reduction in emissions of the hazardous air pollutants subject to this section . . . that the Administrator, taking into consideration the cost of achieving such emission reduction, . . . determines is achievable." The MACT for existing sources in a category or subcategory (with at least 30 sources) must not be less than the average emission level achieved by the best performing 12 percent of existing sources.

[4] A stationary source is defined in CAA section 112(a)(3) as any building, structure, facility, or installation that emits or may emit any air pollutant.

[5] A major source is defined in CAA section 112(a)(1) as a stationary source (or group of stationary sources located within a contiguous area and under common control) that emits, or has the potential to emit, greater than 10 tons per year of any single HAP or 25 tons per year of any combination of HAPs (see footnote 4) .

[6] An area source is defined in CAA section 112(a)(2) as any stationary source of HAPs that is not a major source (see footnote 5). In the context of CAA sections other than 112, this definition may differ.

The air toxics program developed by the Agency in response to this strategy is multi-faceted. In addition to the implementation of technology-based national emission standards on stationary sources of HAPs (see next section), the program contains several risk-based components. The component that is the subject of this Report (and outlined in a subsection below) involves the assessment of post-MACT residual risks under section 112(f) and the promulgation of emission standards, if necessary "to protect public health, . . . or to prevent, taking into consideration costs, energy, safety, and other relevant factors, an adverse environmental effect." Another component that emphasizes reduction of air toxics associated public health risks is the integrated Urban Air Toxics Strategy. This strategy, currently in draft form (EPA 1998a), emphasizes the need to address risks from the cumulative emissions of HAPs from multiple sources and source types, particularly area and mobile sources. The urban strategy seeks to combine the complementary authorities of sections 112(k) and 202(l), and other CAA authorities including 112(f), with State and local authorities to provide a sound basis for the protection of public health from risks posed by area, major, or mobile sources in individual urban areas.

In summary, the 1990 CAA Amendments developed a comprehensive strategy that, when taken as a whole, provides EPA with the flexibility to address a wide range of air toxics problems. The provisions of this strategy describe the approaches for identifying the nature and scope of the problem and provide a diversity of authorities for protecting public health and the environment while managing the identified risk in a cost-effective way.

Emissions Control Under MACT – CAA Section 112(d)

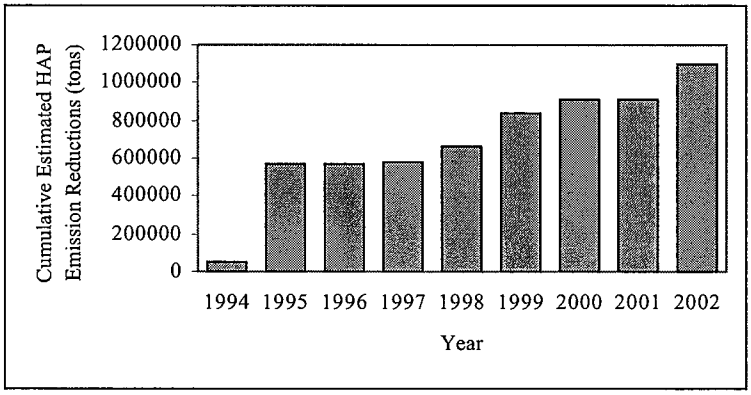
The 1990 CAA Amendments greatly expanded the number of industries that will be affected by national air toxics emission controls; the emission reductions from these controls are just beginning to be realized. Major sources of HAPs, which include large industrial complexes such as chemical plants, oil refineries, marine tank vessel loading operations, aerospace manufacturers, steel mills, and a number of surface coating operations, are some of the sources being controlled for toxic air pollution. Where warranted, smaller sources (area sources) of air toxics such as dry cleaning operations, solvent cleaning activities, commercial sterilizers, secondary lead smelters, and chromium electroplating facilities are also controlled. Within the next six years, EPA estimates that emission standards set under section 112(d) will reduce emissions of toxic air pollutants by well over 1.5 million tons per year.

Regulation of air toxics emissions through the section 112(d) process is beginning to achieve substantial emission reductions of HAPs. The MACT regulations are also resulting in substantial co-control of criteria air pollutants.[7] Appendix C shows a complete list of the section 112 source categories, along with the status of the MACT standard and compliance dates. As of October 1998, 53 source categories have been subjected to standards under section 112. With

[7] Criteria air pollutants are defined as air pollutants for which national ambient air quality standards (NAAQS) have been established under the CAA; at present, the six criteria air pollutants are particulate matter, ozone, carbon monoxide, nitrogen oxides (NO_x), sulfur dioxide, and lead.

some exceptions, sources must comply with the MACT regulations within three years of the effective date of the regulation. **Exhibit 1** shows that the estimate of cumulative reductions expected to be achieved by 2002 with the standards for these 53 source categories is approximately 1,100,000 tons of HAPs per year.[8] Additionally, these regulations will result in estimated emission reductions of approximately 2,500,000 tons per year of particulate matter (a criteria pollutant) and volatile organic compounds (VOCs), a class of ozone precursor.

EXHIBIT 1
PROJECTED ANNUAL CUMULATIVE HAP EMISSION REDUCTIONS



Special Areas of Evaluation

As part of the second phase of the program outlined in the 1990 CAA Amendments, EPA is to conduct specific studies to assess the potential for adverse effects and, if necessary, take action to reduce the potential for these effects. These studies include (but are not limited to) the *Mercury Study Report to Congress* (EPA 1997a), the Great Waters Studies (EPA 1994a, EPA 1997b), and the Utilities Study (EPA 1998b).

In response to CAA section 112(n)(1)(B), the Mercury Study provides an assessment of the magnitude of U.S. mercury emissions by source, the health and environmental implications of these emissions, and the availability and cost of control technologies. Given the continuously and rapidly evolving state-of-the-science for mercury, this Study is considered a "snapshot" of EPA's understanding at the time and identifies research needed to reduce the scientific uncertainty in a number of important areas.

In the Great Waters component of the air toxics program (CAA section 112(m)), the Agency provides Reports to Congress, at biennial intervals, on the atmospheric deposition of

[8] Based on emission reductions as reported in promulgated NESHAPs; see Appendix C: Schedule for Source Category MACT Standards for *Federal Register* citations.

pollutants to the Great Lakes, Chesapeake Bay, Lake Champlain, and certain coastal waters (the "Great Waters"). In cooperation with the National Oceanic and Atmospheric Administration, EPA conducts a program to evaluate the extent of atmospheric deposition of HAPs (and a few other air pollutants) to these waters, investigate sources and deposition rates, and evaluate any adverse effects to public health or the environment caused by such deposition. Research and monitoring are a large part of this program, and the results are summarized in the biennial Reports. In addition, the Reports describe any changes to federal law that have been identified as necessary to protect human health and the environment.

In CAA section 112(n)(1)(A), the Agency was directed to perform a study of "hazards to public health reasonably anticipated to occur as a result of emissions by electric utility steam generating units" of HAPs after imposition of CAA-required controls. In the Utilities Study, HAP emissions test data from a range of utility units (i.e., boilers) along with facility-specific information was used to estimate HAP emissions for all 684 utility plants in the U.S. The risks of priority HAPs and potential control strategies were analyzed and reported. On the basis of this Study and other information, EPA will determine the need to regulate HAP emissions from the electric utility industry under section 112.

Urban Air Toxics Strategy

In recognition that emissions of HAPs from area sources (sources emitting lesser amounts of HAPs than major sources) may "individually, or in the aggregate, present significant risks to public health in urban areas," section 112(k) directs EPA to develop a strategy aimed at reducing such emissions and associated public health risks. The strategy, published in draft form in September 1998 (EPA 1998a), will build on the substantial emission reductions EPA, State, and local governments have already achieved. EPA's MACT-required emission reductions are described in a previous subsection. The Agency also has substantially reduced air toxics emissions through mandated controls on municipal waste combustors, as well as fuel and emission standards for cars and trucks.

The CAA, under section 112(k), requires EPA to develop a strategy for reducing urban air toxics with a focus on stationary sources, including a specific emphasis on area sources. Additionally, under CAA section 202(l), EPA is directed to study the need for and feasibility of controlling emissions of toxics from motor vehicles, focusing on emissions that pose the greatest risk to human health, and, based on this study, to promulgate fuel or vehicle standards. Recognizing the overlapping problems these programs are intended to address, the Agency is evaluting an integrated approach.

Consistent with the requirements of section 112(k), the final strategy will identify a list of at least 30 HAPs that EPA believes pose the greatest threat to public health in urban areas. It will also identify area source categories that are or will be listed under section 112(c) and potentially subject to regulation under section 112(d). Additionally, the strategy will contain a schedule of specific actions to reduce public health risks posed by hazardous air pollutants. These activities will rely on the appropriate regulatory tools implemented by EPA under the CAA or other

federal environmental statutes or by the States. Following consideration of public comment on the draft, the final *Urban Air Toxics Strategy* is scheduled to be published in June 1999.

Residual Risk

To ensure protection of public health and the environment, the 1990 CAA Amendments include section 112(f), which requires a human health risk- and adverse environmental effects-based "needs test" in the second regulatory phase of the air toxics program (see Appendix A for full text of section 112(f)). In this phase, referred to as residual risk standard setting, EPA will consider the need for additional national standards on stationary emission sources following regulation under section 112(d) to protect public health and the environment. Congress directed that such residual risk standards should "provide an ample margin of safety to protect public health."

Section 112(f) also requires EPA to determine whether residual risk standards are necessary to prevent adverse environmental effects, taking into consideration "costs, energy, safety, and other relevant factors" in deciding what level is protective. Adverse environmental effect is defined in section 112(a)(7) as "any significant and widespread adverse effect, which may reasonably be anticipated, to wildlife, aquatic life, or other natural resources, including adverse impacts on populations of endangered or threatened species or significant degradation of environmental quality over broad areas."

In summary, Congress developed a comprehensive strategy that, when taken as a whole, provides EPA with the flexibility to address a wide range of air toxics problems. The provisions of this strategy describe the approaches for identifying the nature and scope of the problem and the mechanisms for involving all concerned parties in discussions. Congress' strategy provides a diversity of authorities for managing the identified risk in a cost-effective way while protecting human and environmental health in the process.

2.3 State and Local Air Toxics Programs

An additional component of risk assessment development has been the emergence of State and local air toxics programs and the interactions that EPA has had with these programs. Prior to passage of the 1990 CAA Amendments, the federal air toxics program progressed slowly. In the absence of a strong federal program, many State and some local agencies began to respond to the air toxics problem by developing their own programs. As a result, many States in the country currently have air toxics control programs in place addressing, at a minimum, new sources of toxic pollutants. Some have their own regulations that allow them to actively control air toxic emissions to a level protective of human health; others rely on comprehensive policies or authority provided to implement the federal program. Some programs are risk-based, while others are technology-based (STAPPA/ALAPCO 1989). State programs may also achieve HAP reductions through regulations developed under CAA section 110 or part D of Title I that control emissions of air pollutants to meet national ambient air quality standards (NAAQS). Various State and local government programs have now been in place for many years and, for some of

the source categories regulated by federal emissions standards under section 112 of the Act, the State or local government programs have likely reduced air toxics emissions and may have succeeded in reducing such emissions to levels at or below those required by the federal MACT standards promulgated under section 112(d).

The State and local programs have focused on three methods for addressing air toxic emissions: (1) ambient air levels; (2) control technology standards; and (3) risk assessment. Over time, many have begun to use combination approaches, such as residual risk assessment, which combines control technology and risk assessment. The main difference between the State/local residual risk assessment approach and the strategy set forth in sections 112(d) and 112(f) of the CAA is one of timing. While the CAA envisions control of HAPs from major sources as a two-step process (MACT followed by residual risk), with the two steps separated in time by as much as nine years, many State and local agencies consider these simultaneously. Both steps are generally completed within the context of a single permit application.

The State and local air toxics programs were invaluable prior to the CAA, and they remain invaluable. The EPA has drawn upon the expertise and experience of State and local agencies to assist in the development of the federal risk program for HAPs. Over the years, more and more State and local air toxics programs have begun to use risk assessment, especially residual risk assessment. In a survey of State and local agencies, conducted in August of 1995, 60 percent of the respondents indicated that their air toxics program was risk-based, and 50 percent of those had residual risk programs addressing both new and existing sources.

Most State and local agencies that are currently using residual risk assessments plan to continue to use them for permitting purposes, so these may be available to EPA as residual risk assessments are prepared on a national basis. The EPA will identify the programs that are currently producing residual risk assessments, the situations in which they are produced, and the type of information contained in the permit applications or accompanying documents in order to add this information to the national residual risk assessment program.

The State and local programs have made progress in addressing the air toxics problem and protecting the health of their people and their environment. A successful residual risk program will be one that integrates the federal program with the State and local programs and strengthens or complements those existing programs. The federal program will need to integrate these existing programs through the interactive sharing of expertise, data, analyses, and methodologies in order to ensure that human health and the environment are protected. Additionally, the State and local authorities may complement the federal program by addressing local risk issues that may not be effectively addressed nationally.

3. Section 112 (f)(1)(A): Methods for Assessing Risks — EPA's General Risk Assessment Approach for Air Toxics

The information presented thus far provides a summary of the legislative and programmatic basis for EPA's air toxics risk assessment process as it exists today. The EPA has refined the process over time using guidance from the reports discussed in Section 3.1, information from and discussions with State, local, and regional air toxics risk assessors, and information and experience gathered from the practical application of risk assessments throughout the Agency. In this chapter, we describe the risk assessment process for air toxics that has developed at EPA. EPA's air toxics program, including residual risk, necessarily will be based on these risk assessment methods, and others that will be developed. The application of these methods to the residual risk assessment process is discussed in Chapter 5. Section 3.1 summarizes the development of human health and ecological risk assessment methods in the federal government and at EPA, Section 3.2 discusses the basic frameworks for risk assessment, Section 3.3 describes how we estimate and characterize exposure, Section 3.4 describes the assessment of human health and environmental effects, and Section 3.5 describes risk characterization.

3.1 Background — Development of Human Health and Ecological Risk Assessment Methods

This section describes some of the history and key events in the development of EPA's air toxics risk assessment methodology, and the general residual risk assessment framework described in this Report. Identifying the nature and scope of the various air toxics problems through data collection, analysis, and mandated studies is an essential step in implementing the post-1990 air toxics strategy. Risk assessment is the primary method to be used in determining the magnitude of potential impacts resulting from continued HAP exposures. In the CAA, Congress included mechanisms that would assist in the development of the residual risk assessment process, including the reports discussed in the next two sections. In developing the air toxics risk assessment methodology, EPA has built on its existing (and continuously evolving) risk assessment policies and guidance, and also has taken into account State and local air toxics risk programs.

3.1.1 National Academy of Sciences Reports of 1983 and 1994

The National Academy of Sciences (NAS) has on several occasions been requested by Congress to evaluate and discuss the processes of risk assessment and risk management. Two of their studies, published in 1983 and 1994, are especially relevant as a foundation for this Report. The emerging practice of risk assessment at EPA and other federal agencies spurred Congress to commission a report from the National Research Council (NRC) of the NAS in the early 1980s. The result was the landmark 1983 study entitled *Risk Assessment in the Federal Government: Managing the Process* (NRC 1983). This report was written at a time when there was an

increasing concern about the risk of cancer resulting from exposure to chemicals in the environment – the fear was that policy might not keep up with the state-of-the-science, which was changing very rapidly in this area.

PURPOSE OF THE 1983 NRC REPORT

The 1983 NRC report was intended to:

- "Explore the intricate relations between science and policy" in the field of risk assessment; and
- "Search for the institutional mechanism that best fosters a constructive partnership between science and government."

The 1983 NRC report recognized the importance of the relationships that exist between science and risk assessment, and between risk assessment and risk management, and undertook the task of clearly defining these relationships. The NRC acknowledged that risk assessment must take full advantage of the available science while maintaining the need to accommodate the various regulatory requirements, and that risk assessment was only one component of the risk management decision process. To define this more clearly, the NRC made a series of recommendations. In general, the NRC recommended the development of specific guidelines for performing risk assessments (at that time, cancer was the main endpoint of concern), that risk assessments developed using the guidelines be reviewed and distributed to the public, and that these risk assessments clearly distinguish the science and policy components from the political, economic, and technical considerations that influence the risk management decisions. This report also provided a description of the health risk assessment paradigm that continues to serve as EPA's model. Partly in response to this report, EPA began a process that continues today of publishing Agency-wide guidelines addressing important areas of risk assessment (see Sections 3.1.3 and 3.1.4).

STEPS INTEGRAL TO RISK ASSESSMENT

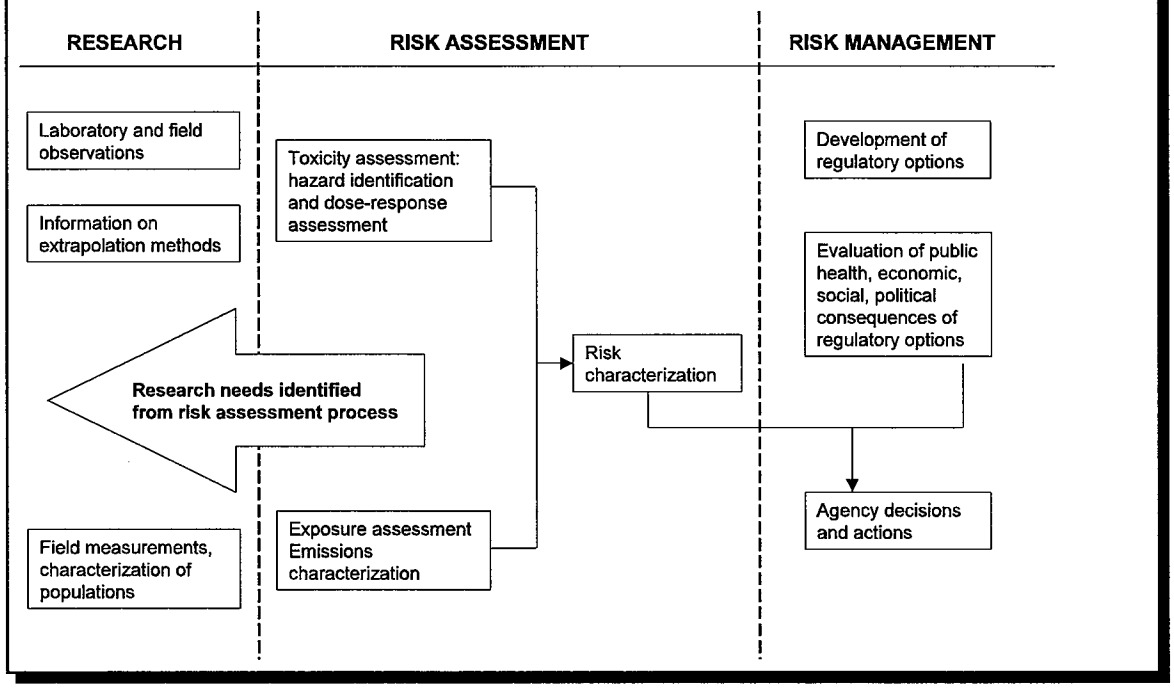
The NRC risk assessment paradigm includes four steps that are integral to any risk assessment (NRC 1983, NRC 1994):

- Hazard identification
- Dose-response assessment
- Exposure assessment
- Risk characterization

The NRC's follow-up report, *Science and Judgment in Risk Assessment* (NRC 1994), mandated by Congress under section 112(o) of the CAA, took a closer look at current risk assessment methods, with a statutorily directed focus on carcinogenic risk. The intent (and mandate) of the report was not to look at EPA's regulatory decisions but the methods used to support those decisions. The NRC committee observed that several themes were common to all elements of the risk assessment process and noted that these themes were usually the focal points for criticisms of specific risk assessments. The themes discussed included the use of default assumptions; the available data; uncertainty and variability; assessment of multiple chemical exposures, multiple routes of exposure, and the potential for multiple adverse effects; and steps taken to validate the methodologies used throughout the risk assessment process. NRC's concerns, discussions, and recommendations were viewed as a way to increase the effectiveness and accuracy of the risk process defined in their 1983 report.

Exhibit 2 shows the risk assessment/risk management paradigm as presented in the 1994 NRC report.

EXHIBIT 2
NRC RISK ASSESSMENT/RISK MANAGEMENT PARADIGM



Source: NRC 1994

The NRC discussed the use of default options in risk assessment, which it defines to be "essentially policy judgments of how to accommodate uncertainties. They include various assumptions that are needed for assessing exposure and risk, such as scaling factors to be used for converting test responses in rodents to estimated responses in humans." Another example of a default option in EPA's cancer risk assessment guidelines is the assumption that cancer risk declines linearly with exposure below the range for which data are available, such that any level of exposure poses some risk. Under current and proposed revisions to these guidelines this assumption is recommended when data are unavailable to support an alternate theory. The NRC concluded that "because of limitations on time, resources, scientific knowledge, and available data, EPA should generally retain its conservative, default-based approach to risk assessment for screening analysis in standard-setting; however, several corrective actions are needed to make the approach more effective." The NRC went on to say:

- EPA should continue to regard the use of default options as a reasonable way to deal with uncertainty about underlying mechanisms in selecting methods and models for use in risk assessment;
- EPA should explicitly identify each use of a default option in risk assessment;
- EPA should clearly state the scientific and policy basis for each default option; and
- The Agency should attempt to give greater formality to its criteria for a departure from default options, in order to give greater guidance to the public and to lessen the possibility of *ad hoc*, undocumented departures from default options that would undercut the scientific credibility of the Agency's risk assessment process. At the same time, the Agency should be aware of the undesirability of having its guidelines evolve into inflexible rules.

The committee recommended that EPA develop and use an iterative approach to health risk assessments to delist source categories and eliminate residual risk. The NRC also proposed a possible iterative approach that will allow for improvements in the default-based approach by improving both models and the data used in each successive iteration of analysis. Furthermore, the committee suggested that EPA present not only point estimates of risk, but also the sources and magnitudes of uncertainty associated with these estimates.

The NRC also discussed how the risk assessment recommendations in its report could be implemented in the context of section 112. Section 112 calls for EPA to regulate HAPs in two stages. In the first, sources would be required to do what is feasible to reduce emissions based on currently available technology. In the second, EPA would set residual risk standards to protect public health with an ample margin of safety if the Agency concluded that implementation of the first stage of standards did not provide such a margin of safety.

The committee indicated that neither the resources nor the scientific data exist to perform a full-scale risk assessment on all the chemicals listed as HAPs and their sources. Therefore, the committee supported an iterative approach to risk assessment of HAPs. This approach would start with relatively inexpensive screening techniques and move to a more resource-intensive level of data-gathering, model construction, and model application as the particular situation warranted. The result would be a process that supports the risk management decisions required by the CAA and that provides incentives for further research, without the need for costly case-by-case evaluations of individual chemicals at every facility in every source category. It also recommended a priority-setting scheme based on initial assessments of each chemical's possible impact on human health and welfare. EPA has been moving, and continues to move, in the directions recommended by this report as it transitions into the risk-based phase of the CAA legislative strategy for HAPs.

3.1.2 CRARM

Section 303 of the 1990 CAA Amendments mandated formation of the CRARM in response to unresolved questions about the approach EPA should take to assessing risks to public

health remaining after implementation of the CAA Amendments' technology-based emission controls. On June 13, 1996, the CRARM released a draft of its report, *Risk Assessment and Risk Management in Regulatory Decision-Making* (CRARM 1996). At the completion of the public comment period, the CRARM announced that it planned to release its final report in two parts. Volume I, released in January 1997, focuses on the framework for environmental health risk management (CRARM 1997a). Volume II, released in March 1997, addresses a variety of technical issues related to risk assessment and risk management, including margin of exposure (MOE), management of residual risks from air toxics, comparative risk, decision criteria, uncertainty analysis, and recommendations to specific agencies (CRARM 1997b).

The CRARM's framework fosters an integrated approach to addressing complex, real-world issues that affect more than one environmental medium and involve exposures to mixtures of chemicals. The CRARM anticipates that its framework will assist Congressional committees and subcommittees, and government agencies (e.g., EPA, DOE), in developing integrated approaches to environmental risk management.

The Commission's Mandate

The Commission's mandate was to investigate "the policy implications and appropriate uses of risk assessment and risk management in regulatory programs under various federal laws to prevent cancer and other chronic health effects which may result from exposure to hazardous substances" (CRARM 1996, 1997a, and 1997b). The CRARM's final report indicated that the Commission's mandate included:

- Assessing uses and limitations of risk assessment and economic analysis in regulatory decision-making (e.g., setting emission, ambient, and exposure standards for hazardous substances);
- Considering the most appropriate methods for measuring and describing cancer risks and non-cancer chronic health risks from exposures to hazardous substances;
- Evaluating exposure scenarios for risk characterization (e.g., use of site-specific exposure data in setting emissions standards);
- Determining how to describe and explain uncertainties (e.g., associated with measurement, extrapolation from animal data to humans);
- Discussing approaches to determining the existence of synergistic or antagonistic effects of hazardous substances;
- Enhancing strategies for risk-based management decisions;
- Considering the desirability of developing a consistent standard of acceptable risk across various federal programs;
- Suggesting ways to improve risk management and risk communication;
- Commenting on the conclusions in the NRC report *Science and Judgment in Risk Assessment*; and
- Making recommendations about peer review.

Although the Commission's mandate was limited to "cancer and other chronic human health effects," the group did discuss ecological risk assessment for the following reasons:

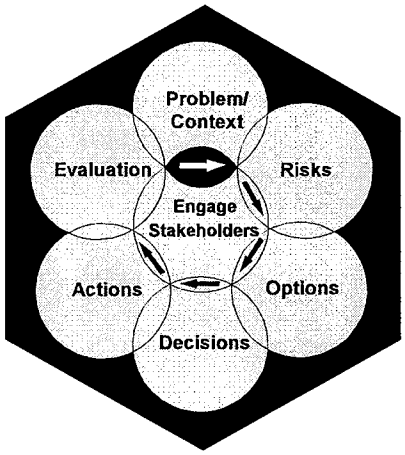
- Human health is related to the health of the environment;
- Principles of health risk assessment are relevant to ecological risk assessment; and
- Economic analyses should not be limited to human health benefits.

The Commission's Report

The final report of the Commission addresses a number of topics, several of which are highlighted below to provide additional context for the residual risk information in this report.

Risk Management Framework. The Commission's framework for environmental health risk management is presented graphically in **Exhibit 3**. The emphasis on stakeholders in this framework is consistent with risk assessment paradigms presented in other recent studies (e.g., NRC 1996). The framework calls for some level of stakeholder involvement during each of the six stages of risk management. In fact, stakeholder collaboration is the central element in the framework. In addition, the framework is designed to be iterative. If appropriate, the risk problem can be redefined and reassessed as new data and new views are found.

EXHIBIT 3
CRARM'S FRAMEWORK FOR RISK MANAGEMENT



Source: CRARM 1997a

Another key principle of the framework is that risk management should explicitly consider the comprehensive real-world context of a risk problem, rather than limit the problem's context to one that considers only one type of risk associated with a single chemical in a single environmental medium. The Commission identified several risk management contexts:

- Multisource context (e.g., the population may be exposed to the same pollutant from sources other than the one in question);
- Multimedia context (e.g., exposure to the pollutant may be occurring from other environmental media);
- Multichemical context (e.g., other pollutants from the same source may pose additional risks); and

- Multirisk context (e.g., the magnitude of risk from one problem may be insignificant compared to similar risks that a population faces from other stressors).

According to the Commission's framework, the relevant contexts for a risk problem are first identified and characterized in the problem/context phase of risk management. These risk contexts are then refined in the risk analysis phase and are addressed in all of the remaining phases of the risk management process.

Comparative Risk Assessment. The CRARM report recommends that federal agencies try a comparative risk analysis approach on an experimental or demonstration basis to seek consensus on priorities for managing environmental risks. The results of such efforts should influence agency resource allocation. The Commission noted that there is wide disagreement on the efficacy of this approach for setting priorities, and that experience shows there is no guarantee that this process will result in consensus among stakeholders, agencies, and funding authorities. However, the Commission also noted that experience shows that the process itself can help to build coalitions that favor priority shifting and shifting resources to identified priorities.

Harmonization of Cancer and Non-cancer Methodologies. The Commission recommended that the assessment techniques for carcinogens and non-carcinogens be harmonized, and discussed the margin-of-exposure and margin-of-protection approaches as ways to do this that would aid in risk communication, risk management decisions and comparative risk assessment. The **margin-of-exposure** approach for expressing risks for carcinogens was recommended as a method which may be more useful for risk managers and stakeholders than the expression of cancer risk in terms of predicted incidence or numbers of deaths per unit population, which can imply an "unwarranted" degree of precision. In EPA's 1996 proposed revisions to the cancer risk assessment guidelines (EPA 1996b), the MOE is defined as the ratio of a specified dose derived from a tumor bioassay, epidemiologic study, or biologic marker study, such as the dose associated with a 10 percent response rate, to an actual or projected human exposure. Lower margins of exposure indicate greater concern. This approach is comparable to the **margin-of-protection** methodology that EPA has used in its "hazard quotient" (HQ) approach for non-cancer risk assessment, which compares an estimated exposure to the estimated acceptable daily intake (ADI), reference dose (RfD), or reference concentration (RfC) value.

Realistic Exposure Scenarios. The report states that risk management decisions should be based on realistic exposure scenarios, rather than on the hypothetical maximum exposed individual (MEI), and supports agencies' recent progress toward this end. It recommends that distributions of population's varied exposures be evaluated with explicit attention to segments of the population with unusually high exposures. The Commission believes that, where possible, exposure assessments should include information about specific groups: infants, children, pregnant women, low-income groups, and minority group communities with exposures influenced by social or cultural practices.

Cost-benefit Analysis. The Commission supports the use of economic analysis as a consideration in risk management decisions, but not as the overriding factor in a decision. The report calls for explicit descriptions of assumptions, data sources, sources of uncertainty, and costs across society to be presented in parallel with descriptions associated with risk assessments.

Interagency Consistency. In conducting risk assessments, agencies should coordinate their risk assessment methods and assumptions unless there is a specific statutory requirement for different choices. Scientific disagreements should be explained.

Residual Risk Recommendations of the Commission

The Commission recommended a tiered approach, which is summarized in **Exhibit 4**, to manage residual risks of section 112 CAA HAPs after implementation of the CAA's technology-based (MACT) standards. Specifically, CRARM proposed that EPA develop their approach in accordance with the five recommendations:

(1) Characterize and articulate the scope of the national, regional, and local air toxics problems and their public health and environmental contexts;
(2) Use available data and default assumptions to perform screening-level risk assessments to identify sources with the highest apparent risks;
(3) Conduct more detailed assessments of sources and facilities with the highest risks, providing guidance and incentives to regulated parties to either conduct these risk assessments or reduce emissions to below screening thresholds;
(4) At facilities that have incremental lifetime upper-bound cancer risks greater than one in 100,000 persons exposed or that have exposure concentrations greater than reference standards, examine and choose risk reduction options in light of total facility risks and public health context; and
(5) Consider reduction of residual risks from source categories of lesser priority.

A specific comparison of EPA's residual risk framework with the Commission's recommendations is presented in Section 5.3.7.

3.1.3 Development of Human Health Risk Assessment at EPA

While the first NRC document on risk assessment in the federal government was published in 1983, EPA has used risk assessment techniques since its inception in 1970. Some quantitative analysis of cancer and other risk was performed prior to 1970 by the Food and Drug Administration and the Federal Radiation Council. The EPA built on this knowledge soon after its inception by confronting potential hazards associated with pesticide use. After considering available human and non-human toxicity data, EPA restricted domestic use of DDT and other pesticides, in part due to their cancer risks. It was acknowledged by EPA that regulations such as these needed appropriate scientific basis, and thus information on the cancer risks associated with these pesticides was collected through administrative hearings and testimony. Summary